



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JAN 21 2004

Mr. Justin Straus
Chief Operating Officer
Cell Tech International Incorporated
565 Century Court
Klamath Falls, Oregon 97601

Dear Mr. Straus:

This is in response to your letter of September 30, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the product **Grape Synergy** uses the claims "...healthy LDL cholesterol..." and "...healthy blood pressure levels."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about control of blood pressure; that is, a claim that does not establish that the claims are about blood pressure that is already within normal limits implies that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claims you are making for this product represent that the product is intended to affect blood cholesterol and blood pressure, but do not also include a statement about it being intended to affect blood cholesterol and blood pressure that are already in the normal range, they are implied disease claims.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases such as heart disease and hypertension. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for

975-0163

LET 746

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Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose
Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink that reads "Linda S. Bellione for Susan Walker, M.D." The signature is written in a cursive style.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

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cc:

all w/copy of incoming

HFA-224

HFA-305 (docket 97S-0163) ✓

HFS-800 (file)

HFS-810 (file)

HFS-811 (Moore w/original incoming)

HFD-40 (Behrman)

HFD-310

HFD-314

HFS-607

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-810:ljw:1/9/04:docname:cell_tech.wpd:H:\Documents:cts: 86777



CELL TECH INTERNATIONAL INCORPORATED

565 Century Court, Klamath Falls, Oregon 97601

Phone: 541.882.5406 Fax: 541.884.1869 www.celltech.com

December 10, 2003

**CERTIFIED MAIL, RETURN
RECEIPT REQUESTED**

Office of Nutritional Product, Labeling and
Dietary Supplement (HFS 810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Notification of Product claims

Dear Sir or Madam:

This letter serves as notification of the nutritional support label statements being made by Cell Tech located at 565 Century Court, Klamath Falls, OR 97601, in connection with products being marketed by Cell Tech. A list of the products and their respective nutritional support statements are listed in the enclosed Attachment "A".

The company hereby certifies that the information contained in this notice is complete and accurate, and that the company can substantiate the statements of nutritional support that are the subject of this notification letter.

If you have any questions, please feel free to contact the undersigned.

Sincerely,


Justin Straus
Chief Operating Officer
Cell Tech International Incorporated

Encl.

86777

- With a broad array of micronutrients (and NO preservatives or stimulants), Resistance is a delicious and refreshing way to support your body's natural defenses.*
- A one-ounce serving of Resistance also contributes to better mental performance, focus, and mood.*
- In addition to vitamins, minerals, and phytonutrients, Resistance provides a wide range of essential amino acids, which feed and enhance brain activity.*
- Resistance will help boost your mind and guard your body.*
- Resistance provides natural support for your immune system.*
- Whether you add it to your favorite beverage or drink it straight, the cinnamon flavor makes Resistance a tasty and refreshing way to enhance your body's natural defenses.*

9. **Product: Grape Synergy**TM

A dietary supplement containing grape seed extract, Super Blue-Green Algae, grape skin extract, Japanese knotweed extract, vitamin C extracts and vitamin E (excipients are rice flour, magnesium stearate, silicon dioxide) in a vegetarian capsule. Grape Synergy is an antioxidant product intended to neutralize free radicals.

Statements of Nutritional Support:

- Red grapes are known to contain many beneficial nutrients, and grape skin extracts are now widely used in the nutraceutical and pharmaceutical industries for cardiovascular support.*
- Other beneficial phytonutrients (plant-based nutrients) found in grape seed and grape skin extract include certain bioflavonoids, polyphenols, and trans-resveratrol, all of which have a highly beneficial impact on circulation and healthy LDL cholesterol and help keep blood thrombocytes flowing freely and normally.*
- Support flexibility of connective tissue (skin and joints)*
- Maintain cardiovascular health, circulation, and cell vitality*
- Improve visual acuity, including night vision, and support eye health*
- Stimulate vascular health of legs and support healthy blood pressure levels*

10. **Product: New Seasons**TM

A dietary supplement system consisting of two formulas as listed below.

Herbal Formula

A dietary supplement containing rice bran, Jerusalem artichoke tubers, milk thistle seed, pumpkin seed, turmeric root, wheat grass, aloe vera gel, amylase,

burdock root, dandelion root, *Echinacea purpurea* root, fennel seed, plantain leaf, cabbage juice powder, cinnamon bark, clove flowerbuds, garlic bulb, ginger rhizome, thyme leaves, blue-green algae (*Aphanizomenon flos-aquae*), cayenne pepper, protease, black walnut leaf, cat's claw bark, cellulase, centaury herb, elecampane root, fenugreek seed, gentian root, grapefruit seed extract, licorice root, yellow dock root, and lipase.